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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,770	12/17/2001	Yoshihito Ikeda	F-7178	2012

277 7590 04/02/2004

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT PAPER NUMBER

1651

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

10/018,770

Applicant(s)

IKEDA ET AL.

Examiner

Francisco C Prats

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1, 4, 6-8 and 10-14.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Francisco C Prats  
Primary Examiner  
Art Unit: 1651

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**ATTACHMENT TO ADVISORY ACTION**

The response filed March 22, 2004, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

All of applicant's argument regarding the pending obviousness rejection has been fully considered but it not persuasive of error. Applicant argues that the lecithin-derived Cu-Zn type superoxide dismutase ("PC-SOD", from phosphatidylcholine superoxide dismutase) possesses properties sufficiently different from non-lecithin derived Cu-Zn superoxide dismutase (SOD or Cu-Zn SOD) such that one of ordinary skill looking to stabilize PC-SOD would not look to methods whereby SOD is stabilized. However, it is respectfully pointed out that PC-SOD possesses more similarities to SOD than differences, and that the similarities are much more relevant to stabilization or storage concerns than the differences.

Applicant's argument ignores the fact that PC-SOD and SOD have numerous properties in common, which would lead the artisan of ordinary skill to stabilize the PC-SOD with the same compounds as used to stabilize SOD. Specifically, the protein portions, i.e., sequence, of PC-SOD and SOD are essentially identical. Thus, except for the few molecules of lecithin

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appended to the enzyme, the two enzymes are in fact the same, not different.

As argued by applicant, the derivatization of the SOD molecule with lecithin moieties provides certain therapeutic advantages to the enzyme, including decreasing the clearance rate of the enzyme once administered *in vivo*. However, applicant does not explain why the artisan of ordinary skill would have looked to the differences in therapeutic properties between the derivatized and non-derivatized enzymes, rather than the actual physical properties of the compounds, to determine suitable stabilizing agents. The fact remains that PC-SOD and SOD are nearly identical molecules. This is evidenced by the fact that both the derivatized enzyme and its non-derivatized counterpart catalyze the same chemical reaction, and therefore have the same therapeutic utility.

Based on catalysis of the same reactions, at the very least the active site of the enzymes are the same. Since preservation of the active site is critical to preservation of the enzyme's activity during storage, one of ordinary skill in the art would have reasonably expected that a compound, i.e. sucrose, which preserved the active site of the non-derivatized enzyme, would have also preserved the active site of the derivatized enzyme. That is, because sucrose was known to inhibit denaturation of

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the active site of superoxide dismutase in general, as disclosed by JP 'the artisan of ordinary skill would have reasonably expected sucrose to have been a useful preservative agent for PC-SOD, which has an identical active site to SOD. Contrary to applicant's argument, one of ordinary skill in the art would not have looked to the clearance rates of the two enzymes as an indication of which preservative/stabilization agent should have been used.

Lastly, as to the alleged different modes whereby PC-SOD and SOD are degraded, applicant has provided no evidence in support of these assertions, and they are therefore merely argument by counsel. In this regard note specifically that argument by counsel is not a sufficient substitute for actual evidence. See, e.g., MPEP § 2145, subsection "I", and cases cited therein. In the absence of actual evidence of unexpected results, the holding of prima facie obviousness is properly maintained.

Further still, it is confusing why applicant asserts that, of the agents disclosed in JP '882, only sucrose is suitable for stabilizing PC-SOD. Table 5 on page 30 of applicant's specification demonstrates that sorbitol-containing and mannitol-containing solutions of PC-SOD are similarly stable to sucrose-containing solutions. Still further, since the claims

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recite the stabilization of PC-SOD with sucrose, any discussion of why other stabilizing agents do not stabilize PC-SOD would appear to be irrelevant. In sum, because the prior art suggests the claimed combination of elements a holding of obviousness is clearly required.

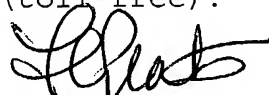
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP